

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE PRAECIS PHARMACEUTICALS, INC. : Civil Action  
SECURITIES LITIGATION : No. 04-12581-GAO  
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**REPLY MEMORANDUM OF LAW  
IN FURTHER SUPPORT OF DEFENDANTS'  
MOTION TO DISMISS THE CONSOLIDATED AMENDED COMPLAINT**

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**PRELIMINARY STATEMENT**<sup>1</sup>

Plaintiffs' opposition<sup>2</sup> confirms that they have no specific facts to support their conclusory allegations of securities fraud. Rather than attempting to put forth arguments defending the allegations of the Complaint, plaintiffs instead populate the Opposition with meaningless adjectives and adverbs to support their conclusory positions. But only specific facts plead with particularity can meet the PSLRA's and Rule 9(b)'s stringent requirements. This failure of pleading is dispositive.

First, far from "more than satisf[ying]" the requirement of pleading fraud with particularity (Opp. at 7), plaintiffs do not (and cannot) offer a single contemporaneous fact supporting why a statement was false when made or what Defendants "knew" at the time. Indeed, plaintiffs almost exclusively rely on alleged facts occurring months after a statement was made to support that an earlier statement must have been false when made. In this regard, plaintiffs make the classic *post hoc ergo propter hoc* logical fallacy. Moreover, plaintiffs' attempt to demonstrate scienter by allegations that the Individual Defendants "must have known" of alleged problems because of their positions within Praecis is contrary to well-settled law in this Circuit. Indeed, throughout the Opposition plaintiffs disregard nearly all of the authority cited by Defendants, relying instead on inapposite cases from other circuits.

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<sup>1</sup> Capitalized terms herein shall have the same meaning as in the Memorandum Of Law In Support Of Defendants' Motion To Dismiss (Docket No. 27) (cited as "Initial Brief at \_\_\_"), filed September 12, 2005. In addition, "App. Ex. \_\_\_" refers to the Appendix Of Public Records (Docket No. 28), also filed September 12, 2005.

<sup>2</sup> See [Corrected] Lead Plaintiffs' Opposition To Defendants' Motion To Dismiss The Consolidated Amended Complaint (Docket No. 35) (the "Opposition") (cited as "Opp. at \_\_\_."), filed October 25, 2005.

Second, plaintiffs mistakenly argue that Defendants' forward-looking statements are not protected by the PSLRA's statutory safe harbor provisions because -- according to plaintiffs -- such statements were not accompanied by meaningful cautionary language and they were, in any event, made with actual knowledge of falsity. Both contentions are conclusory and without merit. Praecis' multiple disclosures concerning the associated risks with the subjects of its forward-looking statements are more specific than similar warnings held to be sufficient in this Circuit. Further, plaintiffs' assertions of "actual knowledge" are conclusory, and not supported by any particularized factual allegations.

Third, while the Opposition now abandons many of the statements alleged to be false and misleading, the remaining statements are all non-actionable as a matter of law because they are either (i) forward-looking and protected by the statutory safe harbor provisions, (ii) immaterial as a matter of law or (iii) not even alleged to be false or misleading.

### **REPLY POINTS**

The Complaint alleges that 18 of Defendants' statements during the putative class period were false and misleading when made. (See Initial Brief at 4 n.2 and Exhibit A attached thereto). The Opposition abandons 8 of those statements (either explicitly or by failing to address them at all), leaving only 10 of Defendants' statements for the Court's consideration.<sup>3</sup> In addition to the Complaint's failure to plead fraud and scienter with the requisite particularity, the remaining statements all are non-actionable as a matter of law. The statements identified in Compl. ¶¶ 108, 109, 114, 120 and 121 are forward-looking, and protected by the safe harbor provisions of the PSLRA. The statements in Compl. ¶¶ 106, 121, 124 and 132 are immaterial as a matter of law,

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<sup>3</sup> The Opposition does not contest Defendants' arguments concerning the statements identified in Compl. ¶¶ 105, 112, 113, 118, 119, 126, 128 and 131.

while the statements in Compl. ¶¶ 106, 107, 120, 127 and 132 are not alleged to be even false or misleading.

**I. THE OPPOSITION CONFIRMS THAT THE COMPLAINT FAILS TO ADEQUATELY PLEAD FRAUD OR SCIENTER**

**A. Plaintiffs' Criticism Of Defendants' Effort To Decipher Their Confusing "Puzzle Pleading" Is Unwarranted, And Further Underscores The Complaint's Lack Of Particularity**

Defendants' Initial Brief sets out (by Complaint paragraph number) the 18 statements that the Complaint challenges as false and misleading. (See Initial Brief at 4 n.2 and Exhibit A attached thereto). The Opposition, however, criticizes Defendants for "absurdly" identifying "¶ 119 as a [sic] alleged misrepresentation," and further accuses Defendants of "discussing only parts of the statements alleged [to be false]." (Opp. at 1 n.2; 11) (emphasis added). Yet the Complaint expressly alleges that ¶ 119 was a false and misleading statement (see Compl. ¶ 122 ("the statements described in 118-121, above, were each materially false and misleading when they were made")). Further, the Initial Brief discusses the bolded portions of statements in the Complaint because, presumably, plaintiffs emphasized those portions to draw attention to them. As to the statements identified in the Complaint as false and misleading that do not have emphasized portions (see Compl. ¶¶ 105, 106, 107, 124, 126 and 131), Defendants (and, presumably, the Court) are left to guess what, if anything, is materially false and misleading about those.

The Complaint is "puzzle-style" in that it groups multiple statements alleged to be false and misleading, then confusingly provides a summary paragraph of alleged reasons why every statement made in every part of the entire grouping was false. (See, e.g., Compl. ¶¶ 110, 115, 122, 125 and 133.) The paragraphs purporting to provide the reasons why statements were false and misleading are plaintiffs' conclusions, which do not even reference allegations elsewhere in the



Complaint, placing the "burden on the reader to sort out the statements and match them with the corresponding adverse facts to solve the 'puzzle' of interpreting [p]laintiffs' claims." In re Splash Tech. Holdings Inc. Sec. Litig., 160 F. Supp. 2d 1059, 1075 (N.D. Cal. 2001) (dismissing complaint and rejecting "puzzle style pleading") (quotation omitted). This "puzzle pleading" fails to satisfy the PSLRA's mandate to plead with particularity each allegedly false statement and the reasons why it was false when made. The Complaint should be dismissed for this reason alone. See In re Autodesk, Inc. Sec. Litig., 132 F. Supp. 2d 833, 842 (N.D. Cal. 2000) (dismissing complaint and holding that "puzzle pleading" does not satisfy particularity requirements).

**B. The Complaint Does Not Support Its Conclusory Assertions Of Fraud With Particularized Allegations**

The Opposition identifies 8 statements that plaintiffs allege were false and misleading (Compl. ¶¶ 107, 108, 109, 114, 120, 124, 127, 132), and cites to certain paragraphs of the Complaint that plaintiffs contend support why those statements were fraudulent (see Opp. at 7-9).<sup>4</sup> But many of those allegations are alleged events occurring months after the statements were made, and thereby violate the rule that "securities fraud cases are decided by a statement-by-statement analysis in which the inquiry made is restricted to the immediate context of each statement . . ." Carney v. Cambridge Tech. Partners, Inc., 135 F. Supp. 2d 235, 243-44 (D. Mass. 2001) (emphasis

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<sup>4</sup> The Opposition does not identify any allegations in the Complaint supporting why the statements identified in ¶¶ 106 and 121 (the remaining 2 statements plaintiffs continue to challenge) were fraudulent. (See Opp. at 7-9.)

added). Moreover, none of those allegations are sufficiently particularized, wholly lacking Rule 9(b)'s requirement that the "particular times, dates, places, or other details of the alleged fraudulent involvement of the actors be alleged." Orton v. Parametric Tech. Corp., 344 F. Supp. 2d 290, 299 (D. Mass. 2004).

**1. Statements Identified In  
Compl. ¶¶ 107-109 And 114 Were Not Fraudulent**

Plaintiffs' support for their challenge to the statement in Compl. ¶ 107 is based on facts that allegedly occurred long after that statement was made in November 2003. (See Opp. at 8 (identifying Compl. ¶¶ 29, 62, 75, 81-90).) Indeed, plaintiffs rely on alleged facts attributed to the "confidential sources" but elsewhere admit that none of those "confidential sources" were even Praecis' employees in November 2003. (Compl. ¶¶ 28-35.) In addition, the Opposition does not even address (much less rebut) Defendants' challenge to the lack of particularity of those same allegations. (See Initial Brief at 25 and 27-28.)

Plaintiffs' citation to "facts" purportedly supporting the alleged falsity of Defendants' potential market and revenue projections (see Compl. ¶¶ 108, 109, 114) similarly fail. (Opp. at 8.) Plaintiffs conclusorily assert that the potential market was far less, as corroborated by "CS No. 3" and "CS No. 7." (Opp. at 8.) But, again, those "confidential sources" were not even employees of Praecis in November 2003, and they refer to events that allegedly occurred months after those statements. Id. In addition, plaintiffs' conclusory assertion that the future market projections "had no basis in fact" is erroneous, and contradicted by plaintiffs' own allegations and documents incorporated into the Complaint. (Opp. at 28.)

Plaintiffs concede that the FDA estimated that Plenaxis® would be available to treat 5-10% of prostate cancer patients. (Opp. at 27-28, Compl. ¶ 2.) Tellingly, plaintiffs omit that

prostate cancer "affects nearly 220,000 patients annually in the United States," making Plenaxis® potentially available to 11,000-22,000 patients per year. (App. Ex. 1 at 6.) Using plaintiffs' pricing and dosing figures in Compl. ¶ 68,<sup>5</sup> that corresponds to a potential revenue opportunity of \$107,800,000-\$215,600,000 based upon prostate cancer patients in calendar year 2003 alone, precisely in line with Defendants' statements at the time, even though Defendants' statements were concerning "long-term revenue opportunity." (Compl. ¶ 114, App. Ex. 4 at 5) (emphasis added).<sup>6</sup>

## 2. **Statements Identified In Compl. ¶¶ 120 And 124 Were Not Fraudulent**

Plaintiffs repeat the conclusory argument that Praecis' internal sales goals were inconsistent with Defendants' forecasts in Compl. ¶ 120, but again do not explain how they were inconsistent. (Opp. at 9.) In addition, plaintiffs put forth non-specific assertions that Plenaxis® "orders . . . were infrequent -- only a few each week," and that pricing programs "failed utterly." (Compl. ¶¶ 70, 76-79.) But nowhere do plaintiffs address -- let alone surmount -- the particularity problems raised by Defendants. (Initial Brief at 26-27.) Plaintiffs' allegations of failed pricing strategies (Compl. ¶¶ 76-79) suffer from more than the fatal lack of particularization: those allegations also fail as a matter of law because they are nothing more than hindsight disagreements with business decisions and, consequently, not actionable as securities fraud. See Van Ormer v. Aspen Tech., Inc., 145 F. Supp. 2d 101, 105-06 (D. Mass. 2000) (dismissing complaint and holding

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<sup>5</sup> Plaintiffs allege that each patient taking Plenaxis® is dosed 3 times in the first 45 days and 1 time every 4 weeks thereafter. (Compl. ¶ 68.) That translates to 14 doses per year, per patient. In addition, plaintiffs allege that a patient is charged \$700 for each dose. (*Id.*) That translates to \$9,800 per patient, per year. Accordingly, (22,000 patients) x (\$9,800) equals \$215,600,000.

<sup>6</sup> Similarly deficient are plaintiffs' allegations that Praecis' internal sales goals made the 2004 sales forecast of \$10 to \$20 million false and misleading. (Opp. at 8.) The Opposition ignores the lack of particularity of those allegations demonstrated in the Initial Brief. (See Initial Brief at 25-26.)

that allegations that revenue projections were not reasonable because defendant "lacked a global cost reporting system" and products were "plagued with technical problems" were "nothing more than complaints of poor management, not securities fraud").<sup>7</sup>

Plaintiffs' argument that the statements in Compl. ¶ 124 (made in May 2004) concerning an "experienced sales force" and "educat[ing]" physicians were fraudulent also are not supported by particularized factual allegations, and are, in any event, not even actionable as securities fraud. The Opposition states that "[b]y then, [Praecis] began to experience voluntary terminations by its experienced sales staff," and cites to Compl. ¶ 122 for that proposition. (Opp. at 9.) But ¶ 122 is not a factual allegation at all. Instead, that paragraph merely recites a hodgepodge of conclusory assertions, not attributed to any source or other particularized indica of reliability. More simply, allegations concerning an inexperienced sales force or low morale are not actionable as securities fraud. Fitzer v. Sec. Dynamics Tech., Inc., 119 F. Supp. 2d 12, 31 (D. Mass. 2000) ("allegations of disruption and dissension in the sales force . . . and inexperienced and poorly-trained sales and service personnel . . . are not actionable under the securities laws") (emphasis added).<sup>8</sup>

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<sup>7</sup> Plaintiffs claim that their conclusory allegations of mismanagement can form the basis of a securities fraud claim. (Opp. at 11-12.) Tellingly, plaintiffs do not attempt to distinguish the dispositive authorities from this Court cited by Defendants. (See Initial Brief at 24, 27.) Instead, plaintiffs cite to inapposite cases outside of this Circuit, none of which involve conclusory assertions of "management by intimidation," failed pricing strategies and low sales force morale alleged here. (Compl. ¶¶ 71-78, 91-95.) See, e.g., In re Sirrom Capital Corp. Sec. Litig., 84 F. Supp. 2d 933, 941-42 (M.D. Tenn. 1999) (holding that alleged false statements concerning "income and shareholder equity and the value and increase in the size of [d]efendants' loan portfolio" are not mere claims of mismanagement) (Opp. at 12).

<sup>8</sup> Plaintiffs' allegation that Defendants' efforts to educate physicians was "an unethical attempt to downplay the serious risks of prescribing Plenaxis in order to expand the drug's limited market" is similarly deficient. (Opp. at 9.) As discussed in the Initial Brief **and ignored in the Opposition**, even if the Complaint's allegations concerning purported off-label sales were sufficiently particularized (and they are not), that is simply not securities fraud. (Initial Brief at 28).

**3. Statements Identified In  
Compl. ¶¶ 127 And 132 Were Not Fraudulent**

When discussing the 2 statements alleged to be fraudulent in July and October 2004 (Compl. ¶¶ 127, 132), the Opposition ignores that Praecis publicly withdrew its 2004 Plenaxis® revenue forecasts months earlier in May 2004. (Opp. at 9, App. Ex. 8 at 2.) Praecis' express withdrawal of those prior forecasts, along with the non-particularized allegations in the Complaint, render those statements incapable of being fraudulent.

Plaintiffs do not support with particularized allegations that the statement in July 2004 that Praecis was seeing a "trend of increasing weekly sales which began in the latter portion of the second quarter" was false and misleading. (Opp. at 9.) Plaintiffs conclusorily assert that Praecis was "experiencing significant product returns, lack of sales, and physician rejection of Plenaxis." (Id.) But none of the allegations that plaintiffs cite even contradict in any manner that Praecis was not in fact experiencing a "trend of increasing weekly sales which began in the latter portion of the second quarter," just as it publicly disclosed. (Id.)

The Complaint's allegations also are not sufficiently particularized to support the assertion that the statements in Compl. ¶ 132 were fraudulent. The Opposition conclusorily asserts that "sales were substantially below expectations," but does not provide what those expectations were, who had them, what bases they had or how much below expectations those sales were. (Id.) Indeed, Praecis had already expressly withdrawn its 2004 Plenaxis® revenue forecasts five months earlier, so there can be no such actionable "expectations." (App. Ex. 8 at 2.) Moreover, the allegations in Compl. ¶¶ 76-78 and 91 are not adequately particularized to support a claim of fraud (and the Opposition does not argue otherwise).

**C. Plaintiffs' Argument That The "Confidential Sources" Are Sufficiently Identified Does Not Cure The Lack Of Particularized Allegations From Those "Sources"**

Plaintiffs' argument that the so-called "confidential sources" are adequately identified misses the point. (Opp. at 23-25.) Defendants did not challenge the descriptions of the "confidential sources" (i.e., who they are), but rather the non-specific allegations attributed to those sources (i.e., what they allege). (Initial Brief at 20-30.) Even if the "confidential sources" are sufficiently described, the allegations from those sources must nevertheless be particularized to support a claim of fraud. See In re Cabletron Sys., Inc., 311 F.3d 11, 30 (1st Cir. 2002) (holding that allegations attributed to anonymous sources were not impermissible "conclusory allegations of fraud, but specific descriptions of the precise means through which [the alleged fraud] occurred") (emphasis added).

The entire section of the Opposition concerning the alleged adequacy of the "confidential sources" only confirms that the alleged facts attributable to those sources are not sufficiently particularized to satisfy the rigorous PSLRA/Rule 9(b) pleading standards. (Opp. at 23-25.) The Opposition repeats the non-particularized allegations that (i) CS No. 1 informed "management" of alleged problems, (ii) CS No. 7 interviewed with a "senior Praecis manager" and allegedly informed that unidentified manager of his "opinion" concerning Plenaxis® market potential, (iii) CS No. 7 had knowledge of "dismal Plenaxis sales" and "significant returns," (iv) CS No. 8 had knowledge of "weak sales" and "infrequent" orders. (Opp. at 25.) Those allegations, however, even if provided by "confidential sources" that are adequately described, are nonetheless woefully inadequate. Van Ormer, 145 F. Supp. 2d at 105 (holding that "[a]llegations supported only by unidentified 'sales managers' who got their information from unspecified sources fall woefully short of meeting particularity requirements."). See also In re Vertex Pharm., Inc. Sec. Litig., 357 F. Supp.

2d 343, 354 (D. Mass. 2005) (dismissing complaint and finding allegations attributed to confidential sources inadequate where those allegations lacked "specific dates" and contained "very vague" descriptions of events).

**D. Plaintiffs' "Scienter-By-Status"  
Argument Is Contrary To Controlling Authority**

Unable to plead "knowledge" with the requisite particularity, plaintiffs argue that "Defendants are presumed to know facts critical to the Company's operations" and cite to Guerra v. Teradyne Inc., Civ. A. No. 01-11789-NG, 2004 WL 1467065, \*27 (D. Mass. Jan. 16, 2004) to support that proposition. (Opp. at 22, 29.) Guerra made no such holding. Instead, that Court analyzed plaintiffs' scienter allegations "[e]ven assuming that this broad assertion is an accurate statement of the law . . . ." Guerra, 2004 WL 1467065, at \*27. But any such "presumption" is not an accurate statement of the law in this Circuit.

Plaintiffs' blanket assertion is contrary to the long-established principle in this Circuit (and others) that a strong inference of scienter cannot be imputed on the basis of an individual's position. See, e.g., Maldonado v. Dominguez, 137 F.3d 1, 9-10 (1st Cir. 1998) (rejecting allegations that defendants must have known facts by virtue of their executive positions). Indeed, the First Circuit recently reaffirmed that principle, rejecting an effort to impute knowledge of alleged fraudulent conduct to a company's chief executive officer and chief financial officer. See In re Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 199 (1st Cir. 2005) ("no strong inference necessarily follows that the Chief Financial Officer, much less the Chief Executive Officer, was aware of the improper proration of future profits on any particular underbid contract").

Moreover, courts in other jurisdictions have flatly rejected the "core business" doctrine at the heart of plaintiffs' assertion of implied knowledge. See In re Read Rite Corp. Sec.

Litig., 335 F.3d 843, 848-49 (9th Cir. 2003) (imputing scienter on basis that "facts critical to a business's core operations or an important transaction generally are . . . apparent . . . to the company and its key officers" would violate the PSLRA) (citation omitted); see also In re Bus. Objects S.A. Sec. Litig., Civ. A. No. 04-2401-MJJ, 2005 WL 1787860, at \*8 n.3 (N.D. Cal. July 27, 2005) (rejecting imputation of scienter based upon core business doctrine as "unpersuasive"); Collmer v. U.S. Liquids, Inc., 268 F. Supp. 2d 718, 754 (S.D. Tex. 2003) (rejecting core business doctrine because it is inconsistent with the "purpose of the PSLRA's particularized pleading requirements").<sup>9</sup> This Court should similarly do so.

## **II. DEFENDANTS' FORWARD-LOOKING STATEMENTS ARE PROTECTED -- ON THIS MOTION TO DISMISS -- BY THE PSLRA'S SAFE-HARBOR PROVISIONS**

Plaintiffs attempt to avoid altogether the clear applicability of the PSLRA's safe-harbor provisions by mistakenly asserting that the safe harbor determination "is unsuitable on a motion to dismiss." (Opp. at 15.) Plaintiffs cite to Asher v. Baxter Int'l Inc., 377 F.3d 727 (7th Cir. 2004) for that proposition, but Asher made no such ruling. (Opp. at 15-16.) In Asher, the Seventh Circuit held that the applicability of the safe harbor could not be determined *in that case*. Asher, 377 F.3d at 734. Asher did not establish a per se rule as plaintiffs would have it. Even if the Seventh Circuit did have such a per se rule, that is not the law in this Circuit. See, e.g., Baron v.

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<sup>9</sup> Most of plaintiffs' cases are inapplicable here because those courts inferred scienter not only on the basis of "core business," but also on the basis of particularized pleadings showing knowledge or recklessness. See Lindelow v. Hill, Civ. A. No. 00-3727, 2001 U.S. Dist. LEXIS 10301, at \*21 (N.D. Ill. July 20, 2001) (scienter inferred based upon particularized facts concerning "what defendants were told regarding the feasibility of launching the site in 1999 and lack of preparation toward that goal"); In re Cell Pathways, Inc. Sec. Litig., Civ. A. No. 99-752, 2000 U.S. Dist. LEXIS 8584, at \*27 (E.D. Pa. June 20, 2000) (court relied on additional allegations sufficient to overcome what it acknowledged as a "prohibition against allegations of knowledge of defendants simply because of their positions in the company") (emphasis added).



Smith, 380 F.3d 49, 53-54 (1st Cir. 2004) (affirming dismissal of forward-looking statements that were identified as such and accompanied by meaningful cautionary language).

**A. Plaintiffs' Argument That Defendants' Statements Concern Current Facts Ignores The Challenged Portions Of Those Statements**

Plaintiffs contend that "most of Defendants' . . . statements are statements of current fact," but ignore the plain language of those statements. (Opp. at 13.) Of the remaining 10 statements plaintiffs continue to challenge, 5 of those statements (or portions thereof) are indisputably forward-looking (Compl. ¶¶ 108, 109, 114, 120 and 121):

- "During 2004, the Company forecasts sales of Plenaxis(TM) to range from \$10.0 million to \$20.0 million and anticipates the ramp-up of revenues to be heavily weighted toward the second half of the year. . . . With respect to the future prospects for Plenaxis(TM), the market for currently available hormonal therapies to treat prostate cancer is approximately \$1.2 billion in the United States. The Company believes that the long-term revenue opportunity for Plenaxis(TM) may represent 15% or more of this market." (Compl. ¶ 114) (1/30/04, App. Ex. 4 at 5) (emphasis added);
- "Although it is early in the Plenaxis(TM) launch, we are encouraged by the feedback from physicians and expect to build sales during the second half of the year as awareness of the product grows among urologists and oncologists." (Compl. ¶ 121) (4/30/04, App. Ex. 6 at 3) (emphasis added);
- "The Company generated net revenue of approximately \$0.4 million through sales to distributors, representing primarily initial stocking levels. Based upon the first quarter activity, the Company's prior Plenaxis(TM) sales forecast of \$10.0 million to \$20.0 million in revenue for 2004 remains unchanged." (Compl. ¶ 120) (4/30/04, App. Ex. 6 at 2) (emphasis added);
- "the current market for hormonal therapy is actually \$1.2 billion in the United States alone. And that represents the combined hormonal therapies that are available for prostate cancer patients. And we've estimated that our drug would be applicable to treat a large segment of that population. And we have estimated somewhere north of 15 to 20 to 30 percent of that size market would be available to patients taking our drug" (Compl. ¶ 109) (11/26/03, App. Ex. 3 at 2) (emphasis added);

- "as we said previously given our market share penetration and also our premium pricing assumptions, we've talked about a 15% plus revenue opportunity of the current \$1.2 billion market and none of that has changed" (Compl. ¶ 108) (11/26/03, App. Ex. 2 at 7) (emphasis added).

Plaintiffs' argument that the statements in Compl. ¶¶ 108-109 are not forward-looking is nonsensical. (Opp. at 14.) The plain language of those statements clearly contemplate potential future revenue of the "hormonal therapy" market, as they discuss that revenue potential based upon internal "pricing assumptions," "estimates" of potential patient population, potential "revenue opportunity" and percentage of a market that "would be available." (Compl. ¶¶ 108-109.) Indeed, even the Opposition recognizes that fact, insofar as it characterizes those statements as discussing the "potential" and "projected" market of Plenaxis®. (Opp. at 14.)

## **B. The Opposition Fails To Overcome The Cautionary Language Safe Harbor**

### **1. Once The Court Determines That A Forward-Looking Statement Is Accompanied By Meaningful Cautionary Language, That Statement Receives Dispositive Protection Under The PSLRA**

Once the Court determines that the statements challenged in Praecis' press releases and conference call transcripts were identified as forward-looking and contained meaningful cautionary language, those statements are deemed non-actionable as a matter of law and any further inquiry ends. See Meyer v. Biopure Corp., 221 F. Supp. 2d 195, 204 (D. Mass. 2002) (dismissing complaint on the grounds that identified statements were forward-looking and cautionary language "identifie[d] the risks at issue in the complaint").<sup>10</sup>

Plaintiffs mistakenly contend that a forward-looking statement accompanied by meaningful cautionary language is not protected by the statutory safe harbor upon a proper pleading

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<sup>10</sup> The statement identified in Compl. ¶ 109 was not accompanied by cautionary language, but nevertheless is protected under the "known falsity" safe harbor. (See Initial Brief at 17-18.)

of actual knowledge of falsity. (Opp. at 20-21.) Plaintiffs cite to several cases in other jurisdictions to support that proposition (see Opp. at 20-23), but once again ignore the most recent decision from the First Circuit, which provides that forward-looking statements accompanied by meaningful cautionary language "escapes liability" even if those statements were "knowingly false and willfully fraudulent." Stone & Webster, 414 F.3d at 212. See also H.R. Rep. No. 104-369, at 44 (1995) as reprinted in 1995 U.S.C.C.A.N. 730, 743 ("[t]he first prong of the safe harbor requires courts to examine only the cautionary statement accompanying the forward-looking statement. Courts should not examine the state of mind of the person making the statement.") (emphasis added).

**2. Far From "General And Unspecific," Praecis' Statements  
Provided Meaningful Cautionary Language About Its Business Risks**

Although plaintiffs conclusorily characterize Praecis' disclosures of risk factors as "general and unspecific" (Opp. at 17), the extensive disclosures referenced in Defendants' Initial Brief at 14-16 more than satisfy what is required by the PSLRA. Indeed, Praecis' cautionary statements are more detailed and specific than those made, and dismissed, in recent cases from this Court:

Statements Made By Praecis	Statements Supporting Dismissal
<p><u>Press Releases</u></p> <p>"This news release <u>contains forward-looking statements</u>, including, but not limited to, . . . the Company's <u>expectations for sales of Plenaxis™ during 2004</u> . . . . These statements are based on the Company's current beliefs and expectations as to future outcomes. <u>Such statements are subject to numerous factors and uncertainties</u>. These include, but are not limited to, the Company's ability to complete the hiring of its sales force and successfully commercialize Plenaxis™, the Company's ability to manufacture Plenaxis™ on a commercial scale . . . <u>as well as the risks set forth from time to time in the Company's filings with the Securities and Exchange Commission</u>, including but not limited to the risks discussed in the Company's Quarterly Report on <u>Form 10-Q for the quarter ended September 30, 2003</u>." (11/25/03, App. Ex. 1 at 7) (emphasis added).<sup>11</sup></p>	<p><u>In re PLC Sys., Inc. Sec. Litig.</u>, 41 F. Supp. 2d 106, 113, 118 (D. Mass. 1999).</p> <p>"Certain of the above statements may be forward-looking statements that involve risk and uncertainties. In such instances, actual results could differ materially as a result of a variety of factors including competitive developments and risk factors listed from time to time in the Company's SEC reports."</p> <p><u>In re Parametric Tech. Corp. Sec. Litig.</u>, 300 F. Supp. 2d 206, 218 (D. Mass. 1999)</p> <p>"Except for the historical information contained herein, matters discussed in this news release may contain forward-looking statements that involve risks and uncertainties that could cause actual results to differ materially from those projected. These include risks and uncertainties that are detailed from time to time in reports filed by [Parametric] with the Securities and Exchange Commission, including the company's most recent reports on Form 10-K and 10-Q. In particular, the company's future results depend upon, among other factors, the level of future orders, market acceptance . . . and weakness in the Asian economies."</p>

<sup>11</sup> The press releases dated November 25, 2003 and April 30, 2004 contain substantially similar language, tailored for the specific content of the release. (See App. Exs. 1 and 6.)

<b><u>Statements Made By Praecis</u></b>	<b><u>Statements Supporting Dismissal</u></b>
<p><u>Conference Call</u></p> <p>"Before getting started I want to remind everyone that – about our news release and Webcast contain forward-looking statements, and these statements are subject to numerous factors and uncertainties. <u>And please refer to the factors set forth in our news release</u> as well as the risks set forth from time to time <u>in our filings with the SEC.</u>" (11/26/03, App. Ex. 1 at 1) (emphasis added).<sup>12</sup></p>	<p><u>In re Parametric</u>, 300 F. Supp. 2d at 219</p> <p>"Before we begin, let me repeat the obligatory safe harbor warning regrading forward-looking statements. Again, as usual, our discussion about the future obviously involve assumptions which may be incorrect. The various [risks] and uncertainties, which could impact our business are spelled out on our form 10Q's and 10K's with the SEC, which you can get from either us or directly from the SEC."</p>

Plaintiffs also attempt to criticize Praecis' cautionary statements in its SEC filings as "variables affecting the business of any company trying to sell a new product," and assert that Praecis did not warn investors of alleged "known" problems with the potential market for Plenaxis®, "pricing structure[s]," and certain FDA imposed restrictions. (Opp. at 19-20.) That argument ignores that Praecis' detailed and specific disclosures quoted in the Initial Brief warned investors of exactly the associated risks that plaintiffs (with the benefit of hindsight) complain of now. (Initial Brief at 14-16.)

### **III. PLAINTIFFS DO NOT REBUT THE IMMATERIALITY AND LACK OF ALLEGATION OF FALSITY CONCERNING THE REMAINING STATEMENTS**

The Initial Brief explained that many of the challenged statements (or portions of those statements) were non-actionable as a matter of law because they were either immaterial or not alleged to be false or misleading. (Initial Brief at 7-10.) By failing to address many of those statements in their Opposition, plaintiffs have conceded that those statements cannot form the basis

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<sup>12</sup> Plaintiffs further argue that this statement was deficient because "it failed to identify" which statements were forward-looking. (Opp. at 18.) That argument would require Defendants to repeat the warning every time a forward-looking statement was being made. This Court considered an identical argument, and rejected it as "almost silly." In re Parametric, 300 F. Supp. 2d at 219.

of a securities fraud claim. As for the remaining 5 statements that are not forward-looking, 2 are immaterial as a matter of law (Compl. ¶¶ 106 and 132) and the final 3 are not alleged to be false or misleading (Compl. ¶¶ 107, 120 and 127).<sup>13</sup>

**A. The Opposition Ignores That General Statements  
Of Corporate Optimism Are Non-Actionable As A Matter Of Law**

Rather than rebut, on a statement-by-statement basis, Defendants' arguments concerning the immateriality of certain statements, plaintiffs mistakenly make a blanket assertion that "[t]he misstatements' materiality is thus shown by the market's reaction to negative news about Plenaxis." (Opp. at 10.) Plaintiffs' apparent argument that each and every statement (or portion of a statement) made in the putative class period is material because of a subsequent drop in stock price is, in a word, nonsense. That argument ignores the well-settled law of this Circuit that "loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker" are non-actionable as a matter of law. Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1217 (1st Cir. 1996).

Four of the remaining statements (or portions thereof) still challenged by plaintiffs are immaterial as a matter of law:

- Plenaxis® approval "will bring a valuable therapy to those patients in the indicated population . . . ." (Compl. ¶ 106) (11/25/03, App. Ex. 1 at 1) (emphasis added).
- "Praecis continued to capitalize on the Plenaxis™ commercial opportunity. Although it is early in the Plenaxis™ launch, we are encouraged by the feedback from physicians . . . ." (Compl. ¶ 121) (4/30/04, App. Ex. 6 at 3) (emphasis added).

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<sup>13</sup> Four of the 10 statements plaintiffs have not abandoned are non-actionable for multiple reasons. (See Compl. ¶¶ 106, 120, 121 and 132.)

- "The first quarter was dedicated to the hiring and training of the 40 person sales force, and this experienced team is now calling on physicians to educate and build product awareness . . . ." (Compl. ¶ 124) (5/25/04, App. Ex. 8 at 1-2) (emphasis added).
- "We are encouraged by the growing base of sales to repeat prescribers. This trend suggests that following their first experience with Plenaxis®, physicians are pleased with the results and thus are continuing to treat existing patients with, and identify new patients for, Plenaxis® therapy." (Compl. ¶ 132) (10/29/04, App. Ex. 11 at 3) (emphasis added).

The statements in Compl. ¶¶ 106, 121 and 132 are the same type of vague and optimistic statements that are routinely dismissed in this Circuit. See, e.g., Orton, 344 F. Supp. 2d at 300-01 (holding that statement "[w]e are pleased with the performance" was non-actionable subjective opinion, and statement that the company was "position[ed] for long-term growth" is a "classic example of non-actionable corporate puffery"). The statement in Compl. ¶ 124 concerning an "experienced sales team" is not only immaterial, but also is not actionable as securities fraud. See Fitzer, 119 F. Supp. 2d at 31 ("allegations of disruption and dissension in the sales force . . . and inexperienced and poorly-trained sales and service personnel . . . are not actionable under the securities laws") (emphasis added).

**B. Plaintiffs Still Challenge Statements Where There  
Are No Allegations That Those Statements Are False And Misleading**

Plaintiffs assert that Defendants' statements identified in Compl. ¶¶ 106 and 107 concerning the PLUS Program were false and misleading when made because Defendants stated that "they would only sell Plenaxis to patients 'who have limited or no other treatment options available.'" (Opp. at 15.) However, the allegations in the Complaint do not support this argument. Indeed, the Complaint alleges that the statements in Compl. ¶¶ 106 and 107 were false and misleading because of Praecis' pricing structures and the Plenaxis® black box warning label.

(Compl. ¶ 110.) The conclusory assertions in Compl. ¶ 110, however, have nothing to do with Defendants' statements referenced in Compl. ¶¶ 106 and 107.

The Opposition also does not challenge the statements in Compl. ¶¶ 120, 127 and 132 concerning trends in Plenaxis® sales. The statement in ¶ 120 that Praecis received net revenue of \$400,000 is not alleged to be false. In addition, while plaintiffs conclusorily assert that Praecis was experiencing "significant product returns," there are no allegations that Praecis was not in fact experiencing a "trend of increasing weekly sales" (Compl. ¶ 127) or a "growing base of sales to repeat prescribers" (Compl. ¶ 132).

#### **IV. PLAINTIFFS MISCONSTRUE THE LOSS CAUSATION ANALYSIS**

To adequately allege loss causation, plaintiffs must allege "that [their] loss [was] caused by the materialization of [a] concealed risk." Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 173 (2d Cir. 2005). In other words, the focus of the inquiry must be on the alleged corrective disclosure, which plaintiffs ignore. (Opp. at 31-34.)

Plaintiffs argue that their allegation that "their losses were fairly attributable to the revelation of the true state of the Plenaxis market" is sufficient to establish loss causation. (Id. at 33.) Not so. First, there is no such allegation in the Complaint (and the Opposition does not purport to cite to any). Moreover, that argument ignores that Praecis' December 6, 2004 public statement informed the market that a prior disclosed risk had materialized. (See Initial Brief at 31-34.) Indeed, Praecis' stock decline reflects the market's reaction to the realization of a disclosed risk, not the realization of a risk previously concealed. That is wholly unaddressed in the Opposition. Thus, as a matter of law, the Complaint fails to adequately plead loss causation.<sup>14</sup>

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<sup>14</sup> Irrespective of which of the many grounds the dismissal of the Section 10(b) claim (Count I) is based upon, the Court's action also mandates dismissal of the Section 20(a) claim (Count II). See Van Ormer, "[w]ithout a violation of section 10(b), there can be no section 20(a) liability." 145 F. Supp. 2d at 108.



**V. NO FURTHER AMENDMENT OF THE COMPLAINT SHOULD BE PERMITTED**

Plaintiffs ask this Court for leave to file yet another amended complaint. (Opp. at 35 n.36.) Plaintiffs' request to engage in an iterative process of filing complaint after complaint should be rejected. It took plaintiffs almost 8 months after filing this case (and 4 months since being appointed lead plaintiffs) to file the Complaint, and then only in response to Defendants' Motion To Dismiss Or, Alternatively, To Require Plaintiffs To File Their Amended Consolidated Complaint Forthwith (Docket No. 14). Even after 8 months of investigation, plaintiffs are only able to "plead their case with determined imagination, but little factual substance." Carney, 135 F. Supp. 2d at 257 (denying request for leave to amend complaint made in a "footnote in [plaintiffs'] memorandum in opposition to [defendants'] motion to dismiss."). Accordingly, the Complaint should now be dismissed with prejudice.

**CONCLUSION**

For all of the foregoing reasons, as well as those stated in Defendants' Initial Brief (Docket No. 27), Defendants' Motion to Dismiss should be granted in its entirety and the Complaint dismissed with prejudice and without leave to further amend.

Dated: November 14, 2005  
Boston, Massachusetts

Respectfully submitted,

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